AUSTRALIS
PHARMACEUTICALS

Corporate Presentation

July, 2025

Australis Pharmaceuticals – Harnessing Nature to Fight Cancer

- Australis Pharmaceuticals (Australis) was founded to develop naturally derived compounds into **cancer therapeutics**
- The original compounds were discovered in honey bee propolis on Kangaroo Island in South Australia and characterized as **microtubule-destabilizing agents (MTAs)**
- **AUS_001, oncology lead compound,** has demonstrated encouraging in-vitro and in-vivo data in efficacy and toxicity studies across multiple tumor lines
- Given the broad anti-cancer activity against solid tumors demonstrated by AUS_001 and the ability to cross the **blood brain barrier**, the Phase 1 study will have a broad inclusion criteria for tumor types
- **Orphan Drug Designation** issued for AUS_001 for **malignant gliomas** in February, 2025 and **Rare Pediatric Disease Designation** issued for AUS_001 for **pediatric high grade gliomas** in March, 2025
- Team in place has strong research and clinical development expertise

Australis Research Focus: The Patients In Need*

	Pancreatic Cancer [1]	Malignant Glioma[2]	Pediatric-type Glioma[3]
US Incidence	66,440	22,654	~8,800
Estimated Survival	12.8% (5 year survival)	~10% (5 year survival)	Most patients do not survive more than 1 – 2 years

No therapies currently in clinical trials identified as having viable potential to address these great unmet needs for patient

*: these represent just a few of the potential tumor types that AUS_001 can target

[1] National Cancer Institute SEER database; [2.] Mesfin, et al. 2024; Ostrom et al., 2022 [3] Gaijjar et al., 2022

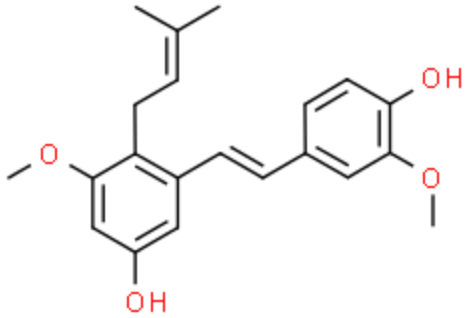
AUS_001: Product Summary

AUS_001 extracted from the sedge plant (source of Kangaroo Island propolis)

AUS_001 Structure

(E-stilbene)

MW=340.42 g/mol



Common name:

(3-[(E)-2-(4-Hydroxy-3-methoxyphenyl)vinyl]-5-methoxy-4-(3-methyl-2-buten-1-yl)phenol

MECHANISM OF ACTION (MOA)*: AUS_001 is characterized as a microtubule-destabilizing agent and has demonstrated cell cycle inhibition and induction of programmed cell death. Reversible mode of target engagement and increased uptake by cancer vs. normal cells

*: MOA data presented at AACR 2024

AUS_001 Differentiators Which Have The Potential To Benefit Patients

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Efficacy

- **Pre-clinical efficacy:** Demonstrated across a range of tumor types, including **glioma and other tumor types representing unmet needs for patients**
- **Crosses the blood brain barrier**

Safety

- **Safety margin: 20-40x** more of AUS_001 needed to inhibit growth of healthy non-neoplastic counterpart cells
- **Peripheral neuropathy**: Reversible neurotoxic effect
- **Drug-Drug interactions:** Poor inhibitor of CYP enzymes, common pathway for drug metabolism

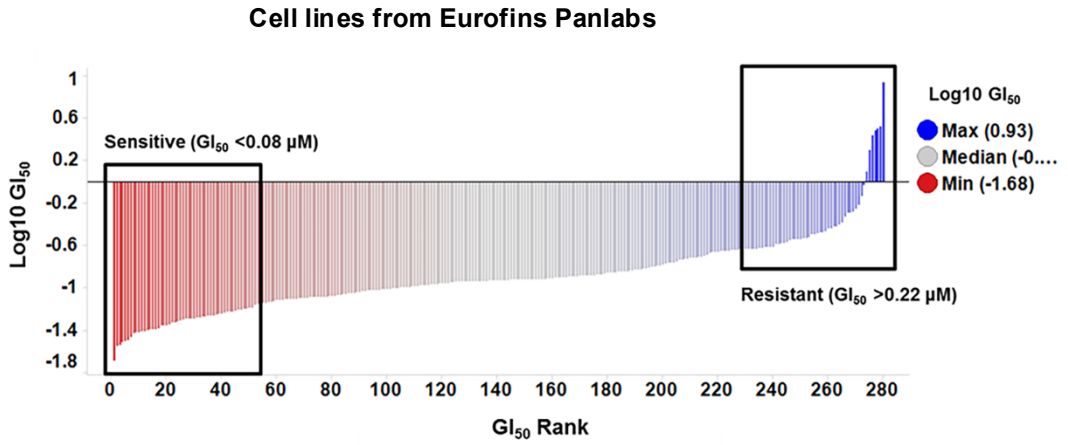
Patient Focus

- **Developing an oral formulation**
- **Potential balance of efficacy and safety,** based on pre-clinical therapeutic index

Data Summary for AUS_001: Encouraging In Vitro Data

In Vitro Data

- High potency against **24 types of cancer*, including glioblastoma and other tumor types representing unmet needs for patients**
- Encouraging safety margin: **20-40x** more of AUS_001 needed to inhibit growth of healthy non-neoplastic counterpart cells
- Reduced concern for **peripheral neuropathy**: Drug treated midbrain and cortical neurons showed reversible neurotoxic effect for AUS_001 but Paclitaxel-treated neurons suffered sustained neurotoxicity even after discontinuation of treatment
- Less susceptibility to **Drug Resistance-related mechanisms**



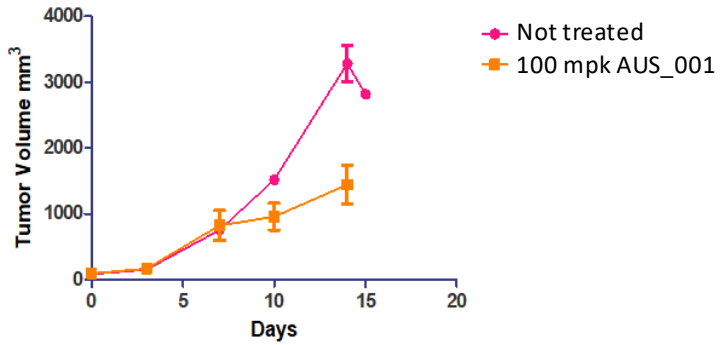
The proliferation response of 280 cancer cell lines to AUS_001 treatments as assessed by high-content fluorescence imaging (Eurofins Panlabs): All cell lines with cell count GI50 <0.08 uM were classified as sensitive to AUS_001, while those with GI50 >0.22 uM were classified as resistant.

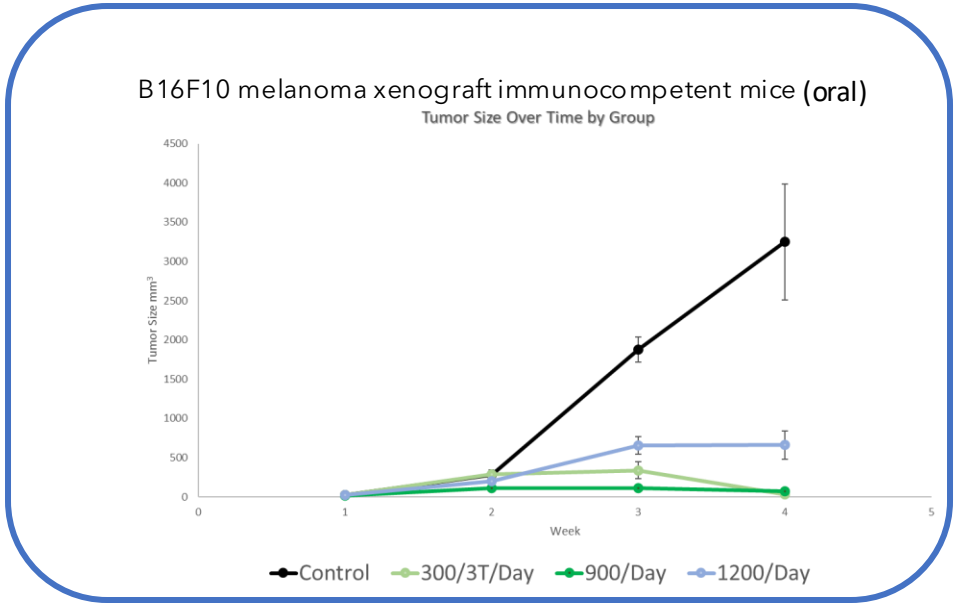
*as viewed in 273 of 280 Cancer Cell lines

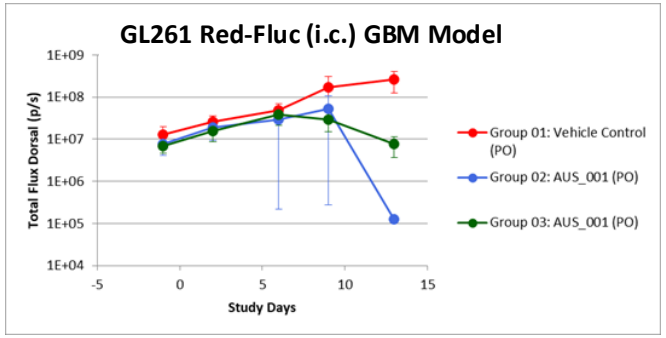
Data Summary for AUS_001: Encouraging In Vivo Data

In Vivo Data

- Efficacy established in 7 different in vivo cancer models*
- Crossing of blood-brain barrier**
- Pharmacokinetics/Pharmacodynamics: Accumulation in tumors, organs and brain tissues
- Lack of myelosuppression or other overt toxicities in immunocompetent mouse study (21 days, P.O.)
- Non-emetic response in ferrets







*: Figures to the right depict a few in vivo models; Additional data available upon request

**: Assessed using the 3D Human Blood Brain Barrier Model

Safety AUS_001 demonstrated an encouraging safety profile in Predictive Toxicology Screen

Toxicology Study	Results
AMES Test	No mutagenic potential up to 100 µM doses of AUS_001
Liver	Poor inhibitor of CYP enzymes, except for CYP1A
Cardiovascular	Low hERG-blocking liability with a half-maximal inhibitory concentration of 65 µM
P-glycoprotein (P-gp) model	P-gp overexpressing cellular models do not confer resistance to AUS_001
Vascular	AUS_001 affects activated Human Umbilical Vein Endothelial Cells (HUVECs) at lower doses relative to those required for cytotoxicity induction of quiescent endothelial cells

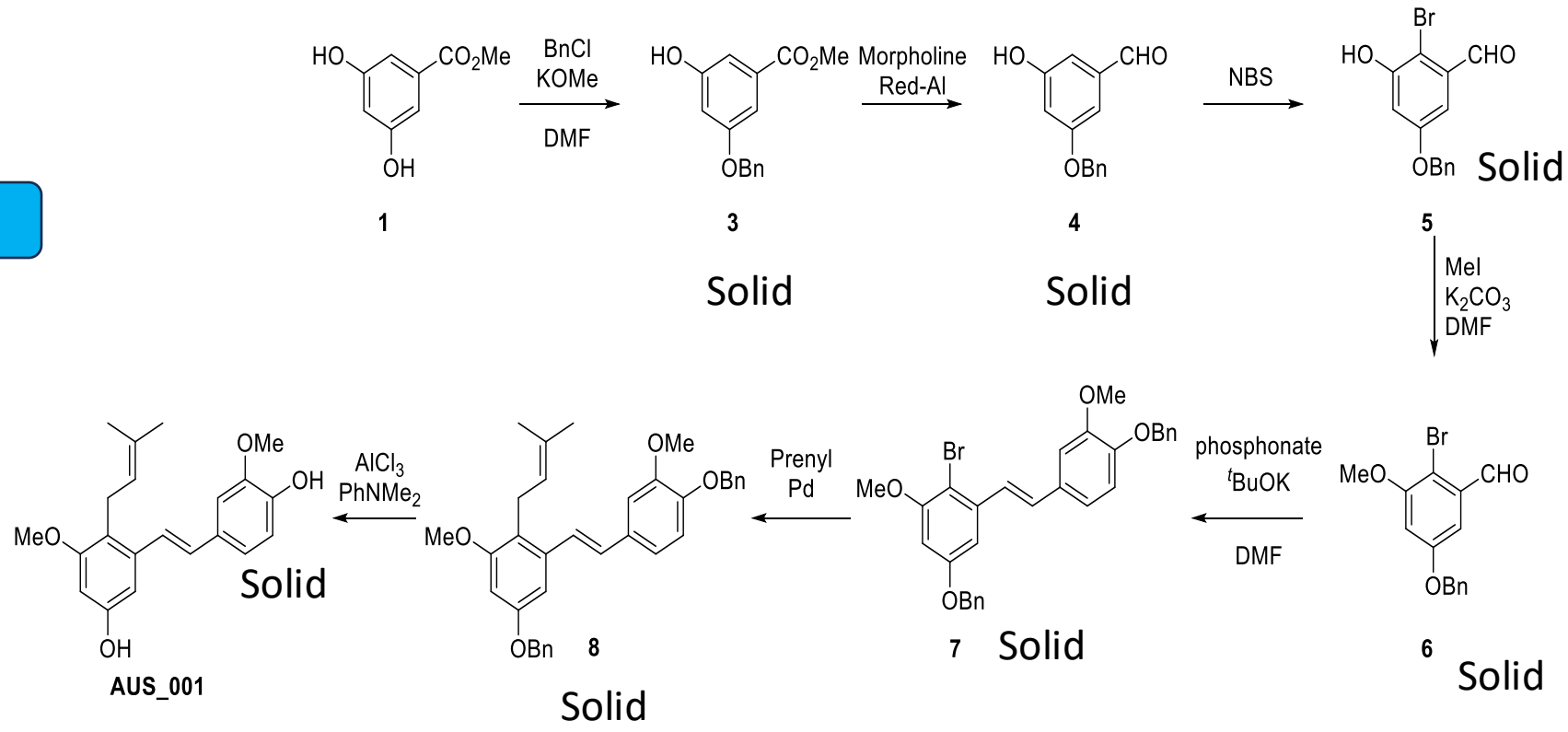
The results of these studies are all encouraging and have a low level of concern for potential patient impact

Chemistry and Manufacturing Established for AUS_001

Synthesis and Manufacturing

- 9 step synthesis of drug substance established -- see figure below
- Currently developing scalable manufacturing (no chromatography)

Synthesis Process



AUS_001 Data Accepted for Presentation at Multiple Peer Reviewed Meetings

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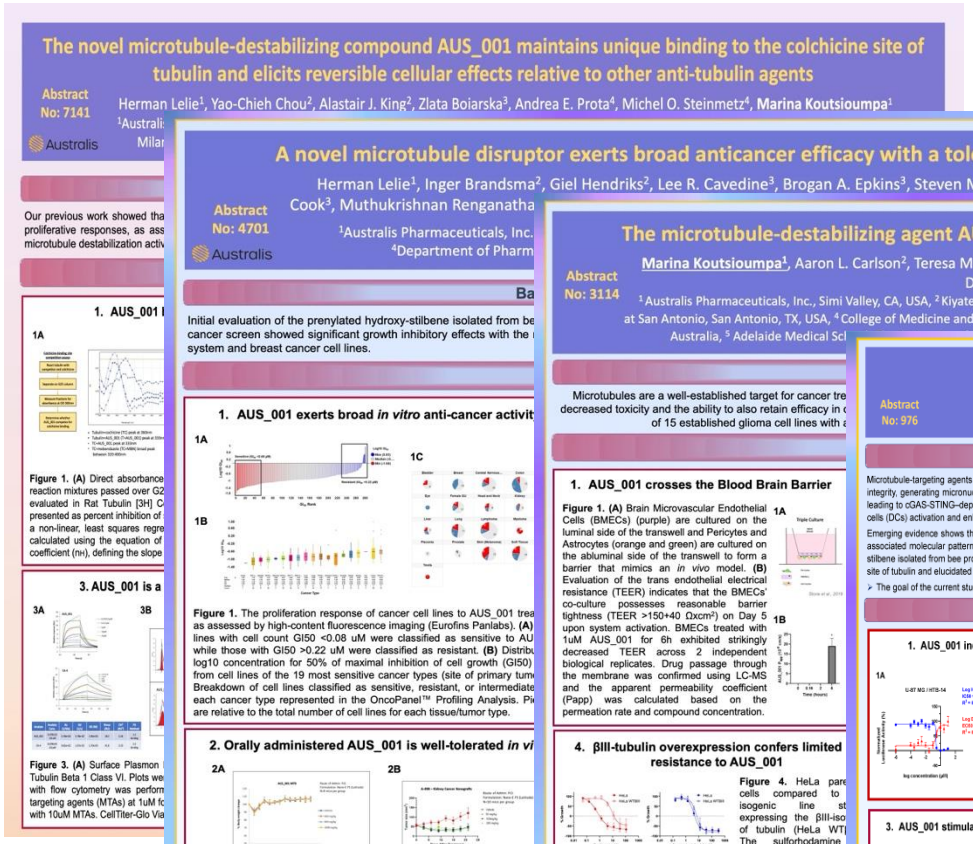
AACR 2024

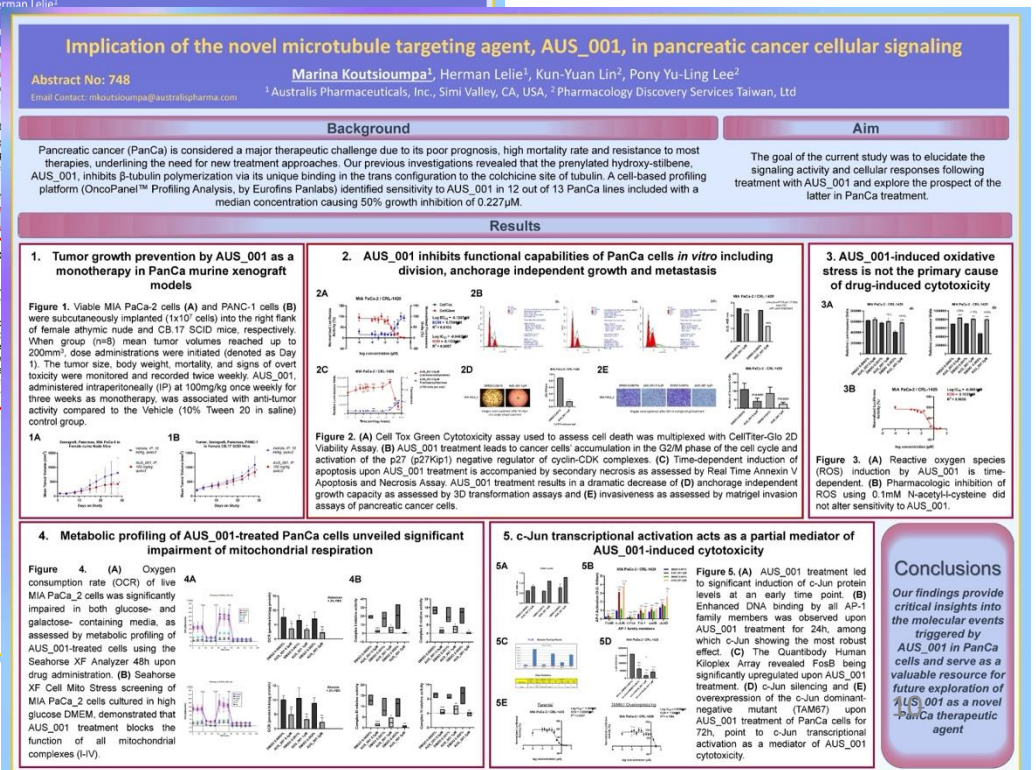


AACR 2024

ASCO 2024

SITC 2024

ASCO GI 2025



AACR: American Association for Cancer Research
ASCO: American Society of Clinical Oncology
SITC: Society for Immunotherapy of Cancer

Intellectual Property

Global Patents/Exclusivity	Expiry
2012: Use and synthesis of AUS_001 and one pipeline asset	2032
2020: Covers 4 pipeline assets, new synthesis route and 5000+ potential new chemical entities	2040
Orphan Drug and Rare Pediatric Designations	~ 7 year extension following approval

Australis Pharmaceuticals Timeline

2020 - 2024

- In vitro and in vivo data demonstrating efficacy and safety
- Mechanism of action characterized
- Pharmacokinetic, absorption, distribution, metabolism, and excretion data generated
- First abstracts and posters presented at medical meetings, including work with academic partners
- Toxicology testing – 14 day dose response

1Q2025

- Orphan Drug Designation received
- Rare Pediatric Disease Designation received

2Q2025

- Scalable GMP manufacturing
- Dose Range Finding/GLP Toxicology initiated in rodent
- Continue to advance in vivo data in glioma and pediatric high grade glioma: partnerships with Mayo Clinic, Children's Hospital, and Newcastle (Australia)

3Q2025 (planned)

- GLP Toxicology in mini – pig
- FDA Pre-IND meeting

4Q2025 (planned)

- FDA IND submission
- Ready for Australia first in human study

Australis Pharmaceuticals Executive Team

Team Member	Role	Expertise	Past Experiences
Todd Robinson	Founder	Entrepreneur with business and financial expertise. Owner of the land where AUS_001 was discovered	Building and leading organizations across many industries
Michele Korfin, RPh, MBA	CEO	~30 years as a Biotech leader	Merck, Celgene, Kite, TYME, Gamida Cell
Caroline Carr, CPA	CFO	Finance leader in Biotechs and Pharma companies	Mycovia, Dara, Pfizer, Deloitte
Marina Koutsioumpa, PhD	VP, Cancer Biology	PhD with expertise in cancer biology and molecular pharmacology	UCLA Center for Systems Biomedicine
Herman Lelie, PhD	VP, Research and Development	PhD with expertise in analytical chemistry and pre-clinical development	MIT, UCLA, Bruin Biometrics, Constitution Labs

Australis Pharmaceuticals Funding

Successfully raised ~$30M over the last 10+ years

No debt on the balance sheet

Enough cash on hand to proceed through Phase 1

Australis Pharmaceuticals – Summary and Next Steps

- AUS_001 has demonstrated encouraging pre-clinical efficacy with a large safety margin
- Completing IND enabling studies this year and will plan to be ready for first in human studies by the end of 2025
- Experienced scientific team who have partnered very effectively with academic institutions
- Leadership team with expertise in advancing oncology therapies through FDA approval and launch
- Business goals for 2025:
  - Biotech/pharmaceutical partnerships to advance our clinical research
  - Continue to enhance our balance sheet for our clinical trial work beyond first in human